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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,329

01/29/2004

Sean D. Monahan

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05/17/2006

MIRUS CORPORATION
505 SOUTH ROSA RD
MADISON, WI 53719

EXAMINER

VANIK, DAVID L

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,329

Applicant(s)

MONAHAN ET AL.

Examiner

David L. Vanik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of the Applicant's Remarks and Amended Claims filed on 3/1/2006. Receipt is also acknowledged of Applicant's Request for Continued Examination filed on 3/1/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims 1-8, 21-24 have been amended to encompass the limitation of "polypeptide-detergent." This term is not set forth in the instant specification and, as such, is considered to be new matter. Moreover, after electronically searching the instant specification, the only mention of "detergent" is in the definitions portion of the text (See pages 13-14 of the instant specification). Since, the instant application is concerned with polypeptide-surfactant complexes and the amended claims read on a more narrow "polypeptide-detergent"

limitation, the newly amended claims fail to comply with the written description requirement.

Response to Arguments

Applicant's arguments filed 3/1/2006 have been fully considered but they are not persuasive. In response to the 1/12/2006 Final Rejection, Applicant's assert that '329 sufficiently disclose a "polypeptide-detergent complex" as evidenced by the examples and definitions set forth in their disclosure. While the examiner notes the definitions and specific examples set forth in the instant disclosure, the examiner respectfully submits that the instant disclosure is insufficient to support the generic limitation of dried noncovalently associated polypeptide/detergent complexes.

With respect to Applicant's arguments, the examiner respectfully submits that the limitation "dried polypeptide-detergent" does not satisfy the written description requirement. Specifically, the examples referred to in the 3/1/2006 response to the Final Rejection (cetylpyridium bromide, cetyltrimethylammonium bromide, dodecylpyridium bromide, dodecyldimethylammonium bromide, dodecyltrimethylammonium, cetyldimethylethylammonium bromide, and topss) are referred to as "positively charged surfactants" in the instant disclosure (page 8, lines 8-16). Moreover, although "surfactant" and "detergent" are defined in the instant specification, the examiner respectfully asserts that a "dried polypeptide-detergent" in its generic form is not set forth in the instant disclosure. As a result, the examiner

respectfully asserts that the limitation "dried polypeptide-detergent" does not satisfy the written description requirement.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a limited class of detergents - polypeptide complexes, wherein the surfactant is chosen from cetylpyridium bromide, cetyltrimethylammonium bromide, dodecylpyridium bromide, dodecyldimethylammonium bromide, dodecyltrimethylammonium, cetyldimethylethylammonium bromide, and topss, does not reasonably provide enablement for the generic class of "dried polypeptide-detergent" complexes as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The examiner acknowledges that the Applicant should not be limited to the examples or specific embodiments in the specification. However, the limitation "dried polypeptide-detergent" is extremely broad and encompasses an extremely large class of compositions that are not taught by the instant disclosure. As such, the disclosure of the instant specification is not sufficient to support the generic concept of "dried polypeptide-detergent." In short, based on the

instant disclosure, the examiner respectfully submits that one of skill in the art would be faced with an undue amount of experimentation in attempting to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0335133 A2 ('133) as evidenced by US 5,939,536 ('536).

'133 disclose compositions comprising surfactant proteins and phospholipids (abstract). Said protein-based compositions may be attached to a lipid via a non-covalent or covalent bond (page 3, lines 24-27 and page 4, lines 7-18). The compositions contain cell-targeting signals, as they are capable of delivering of the protein/lipid complex to the lungs (page 3, lines 12-13). It is the examiner's position that the surfactant vesicles used to transport proteins to the lungs are liposomes (page 3, lines 24-27).

According to '133, one type of phospholipid suitable for use in the surfactant protein/phospholipids mixture is phosphatidylcholine (page 2, lines 25-26). As

evidenced by '536, phosphatidylcholine is a detergent (column 4, lines 8-15).

Depending on the "R" groups attached to phosphatidylcholine, said phosphatidylcholine can comprise a hydrophobic alkyl chain of 4 to 30 carbons. Thus, like the instant claim 1, '133 disclose a detergent/polypeptide complex.

In terms of the process of preparing said lipid/peptide complex, leuprolide, a nanopeptide, was admixed with lipids, phospholipids, and detergents (page 5, line 15-25). The solvents were then evaporated (page 5, lines 20-23). It is the examiner's position that, after evaporation of the solvents, the peptide/lipid complex was dried. After the solvent was evaporated from the peptide/lipid complex, a small quantity of ethanol, an aqueous solvent, was added to the complex (page 5, lines 20-23). After the preparation of said lipid/peptide complex, the dispersion was administered to a subject (page 6, lines 15-29). Specifically, the drug complex was delivered to dogs via a catheter (page 6, lines 28-29). Since the drug complex was administered to dogs via the "permanent stoma near the bifurcation of the major bronchi," the examiner respectfully submits that cells were necessarily "contacted" with the drug complex.

The claims are therefore anticipated by EP 0335133 A2 ('133) as evidenced by US 5,939,536 ('536).

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,858,398 ('398) as evidenced by US 3,578,591 ('591).

'398 disclose pharmaceutical compositions comprising (1) phospholipids, (2) surfactants, (3) sterols, (4) pharmaceutically active agents, and (5) fatty acids having a chain length of C1 to C14 (Claim 1). According to '398, proteins, such as insulin, may be used as the active agent and surfactants, such as sorbitan monooleate, sorbitan sesquileate, and sorbitan monolaurate, may be used in the composition (Claims 1-2 and Example 1). As evidenced by '591, sorbitan monooleate, sorbitan sesquileate, and sorbitan monolaurate are all suitable detergents (column 6, lines 26-40). Like the instant claim set, the polypeptide complex advanced by '398 may be noncovalently bound and may be in "dry" form (column 12, lines 56; column 19, line 65 – column 20, line 5; and column 20, line 48). Sterol-based compounds are also added to the composition in order to increase the compositions "adherence to absorptive cells" (column 15, lines 35-54).

'398 also set forth a process for making and using the above composition (Example 1; column 19, line 11 – column 20, line 52). According to '398, an insulin peptide may be combined with phospholipids, sterols, and surfactants (including the above detergents) and said complex may be dissolved in an organic solvent (Example 1). The polypeptide complex may then be dried (column 19, line 65 – column 20, line 5 and Example 3). After preparing the polypeptide-complex, said complex can be dissolved in a suitable solvent and contacted with cells (column 26, lines 25 – column 27, line 60).

The claims are therefore anticipated by US 5,858,398 ('398) as evidenced by US 3,578,591 ('591).

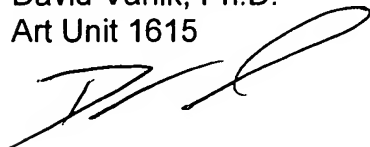
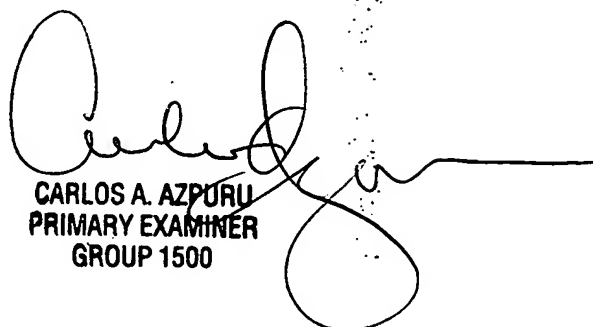
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615


5/12/06
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